OCULUS
BIOM 4

INSTRUCTION MANUAL

Binocular Indirect OphthalmoMicroscope

OCULUS®

Notes on this instruction manual

Thank you for your purchase and the trust you have placed in this OCULUS product. The BIOM 4 has been manufactured and tested according to strict quality criteria. You have selected a modern and well-engineered product.

The Binocular Indirect Ophthalmomicroscope, BIOM 4, is an advancement of the BIOM.

It successfully combines an ophthalmoscope with an operating microscope. Without corneal contact, it provides an optimum image of the vitreous space under stereoscopic conditions with a panoramic, up to 120° view of the fundus.

To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarise yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

This operating manual describes the following BIOM 4 models:

- BIOM 4c and 4cl (long version)
- BIOM 4m and 4ml (long version)

  Except for the difference in length, the respective long version is identical with respect to handling and features. The long version should be used on microscopes with focal length of 200 mm or more.

Due to ongoing development, the diagrams shown in the instruction manual may depict minor changes to the actual device delivered.

If you have any queries or would like additional information about your device, do not hesitate to call or send us a fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

OCULUS is certified according to DIN EN ISO 9001:2000 and 13485:2003, setting high standards of quality where development, manufacture, quality assurance and service regarding the entire range of products are concerned.

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1 Scope of Delivery

BIOM 4m

Component
■ BIOM 4m
■ Instruction manual
■ Box with cover
■ Conditioning manual

BIOM 4c

Component
■ BIOM 4c
■ Sterilizable drive belts (10 of)
■ Sterilizable cable duct
■ Drive unit as spare part (item no. 54405)
■ Instruction manual
■ Box with cover
■ Conditioning manual

Supplementary components needed for BIOM 4c and 4m

Needed supplementary components
■ Reduction lens and ophthalmoscopy front lens
■ Adapter for operating microscope (if necessary, with additional adaption modules).
■ Stereoscopic diagonal inverter for erecting the image

➔ Please read the special packing notice included with the adapter and accessories.

➔ If you have also selected our company's Stereoscopic Diagonal Inverter (SDI 4), you will find this unit and its accessories in a lined plastic carrying case.

➔ Please read the separate operating instructions for the SDI 4 and accessories.

Note

We reserve the right to change the scope of delivery in line with ongoing technical development.

2 Safety Instructions

2.1 Pictogram definitions

Attention

Indicates a potentially hazardous situation that can result in injury or material damage.

Note

Instructions for use and useful or important information.

Note

Identifies important information about the product or on how to use it, which requires special attention.

2.2 Safety instructions concerning organisation

The law requires that the manufacturer expressly informs the user about safety aspects concerning the handling of the device. This chapter contains a summary of the most important safety-related information.

Attention

Do not operate the unit until you have read and fully understood the entire instruction manual.

- ➔ Make sure to keep this instruction manual in a safe place and available to operating personnel at all times.
- ➔ Observe the legal regulations with regard to accident prevention.
- ➔ The unit must not be used if a fault occurs that you cannot rectify. Get in touch with our service personnel.

Attention

Heed unconditionally the instruction manual and safety advice of the operating microscope and of the additional equipment. Familiarize yourself with all safety features and devices before you put the unit into initial operation.

2.3 Safety instructions for use of the BIOM 4

Note

Before putting this instrument into operation for the first time, the user must be familiarized with it by an Oculus Optikgeräte GmbH representative or an authorized dealer.

Attention

No modifications may be made to this device without the permission of the manufacturer.

- Only operate the device using original accessory parts supplied by us, and when the device is in technically correct working order.
- Do not use the unit if it is damaged; in this case, get in touch with your supplier.
- Observe the legal regulations with regard to accident prevention.
- Also comply with the legal provisions in force in your country, and with the hygiene and waste disposal regulations of the hospital or clinic.
- If a fault occurs that you cannot rectify with the help of the troubleshooting table *(sect. 8, page 22)*, the unit must not be used. Clearly mark the unit as non-operational and get in touch with our service personnel.
- **The BIOM and all sterilizable BIOM components must be sterilely conditioned prior to the first, and every subsequent use.**
- It is imperative that you heed the cleaning, disinfection and sterilization instructions given in the "conditioning manual".

Attention

After the BIOM 4 has been swung in into the working position, the following must not be performed during the proper use:

- ➔ to use the rough adjustment mechanism of the microscope support under any circumstances (since the mechanism is not designed for precisely controlled movement)
- ➔ to change the height position of the microscope support by mechanical or motorized means whilst above the operating area
- ➔ to change the patient´s position by raising/lowering the OP-table

2.3.1 Safety instructions for focusing the BIOM 4

Attention

The following points must be heeded when focusing the BIOM 4:

- The BIOM 4 is only needed for visualization of the posterior segment of the eye.
- After performing the operation steps at the anterior segment of the eye and outside of the eye, the microscope should be remaining at this position (height).
- Before swinging it to the operating position, make sure that the BIOM has been set to the shortest overall length.
- Before you begin to focus the BIOM 4, check the distance from the ophthalmoscopy front lens to the patient's eye.
- Monitor the distance between the front lens and the eye while focusing the BIOM 4.
- Make sure that the ophthalmoscopy front lens does not come into contact with the eye.
- The microscope must not be adjusted in height, nor must the focusing function of the microscope be used while the BIOM is being focused.

For BIOM 4c only (focusing done by electric motor):

- Only use the motorized BIOM focusing function when the ophthalmoscopy lens is far enough away from the eye.
- The motorized focusing function of the BIOM 4c may only be used by the surgeon, when this distance is *simultaneously* monitored.
- It must be ensured that the operator can stop the motorized focusing function at any time.

3 Proper Usage

This binocular indirect ophthalmomicroscope (BIOM 4) is used for non-contact observation of surgeries in the posterior segment of the eye.

The BIOM 4 should be used only by physicians and OP personnel who have been correspondingly trained and who have the training, knowledge, and practical experience to ensure appropriate handling.

The BIOM 4 is intended for use with compatible designed operating microscopes in hospitals, clinics or other institutions for human medicine.

Use only operating microscopes named by OCULUS Optikgeraete GmbH as adaptable for the BIOM 4.

Only operate the device using original accessory parts supplied by us, and when the device is in technically correct working order.

Please note carefully all safety information in this manual.

4 Transport of the BIOM 4

- ➔ Avoid shock/vibration when transporting the BIOM 4 and the optical modules to a different location.
- ➔ Check the unit and its accessories for damage after every transport.

5 Device Description

5.1 Overview of device components

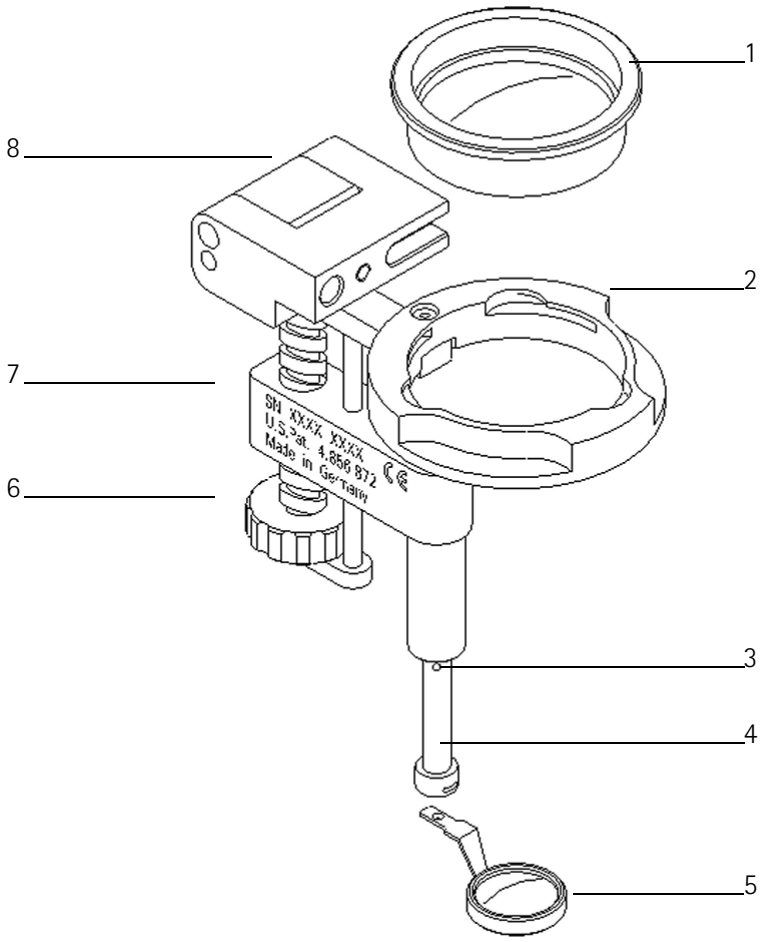


fig. 5-1: BIOM 4m with reduction lens and ophthalmoscopy front lens

1 *Reduction lens (not supplied with the BIOM)*
2 *Lens receptacle*
3 *Control mark*
4 *Lens holder with safety slider*
5 *Ophthalmoscopy lens - so called front lens (not supplied with the BIOM)*
6 *Focus adjustment wheel*
7 *Bridge*
8 *Housing with swivel mechanism*

5.2 Mode of operation of the BIOM 4

The BIOM 4 is used in conjunction with an SDI (Stereoscopic Diagonal Inverter) to erect the image for non-contact, wide-angle observation of the fundus and vitreous body.

The combination of operating microscope and the optical components of the BIOM 4 allows examination of the vitreous body in the posterior chamber under stereoscopic

conditions. The BIOM 4 works as an indirect ophthalmomicroscope without corneal contact during the surgery.

The patient's eye ball can be moved freely during the surgery. Peripheral fundus portions are thus easy to examine. This combined optical system achieves a fundus view of up to 120° in total.

The optical system of the BIOM 4 consists of the reduction lens and the front lens. The reduction lens provides a virtually constant distance between the patient's eye and the operating microscope when the BIOM 4 is swung in or swung out. Individually adjusted to the respective operating microscope, the microscope objective's focal distance is reduced.

The position of the reduction lens with respect to the operating microscope is preset.

The height adjustment of the front lens is used for focusing the BIOM image. The distance between the operating microscope and the front lens is set using the adjusting wheel at the BIOM 4.

For BIOM 4c only:

Press the combination foot switch to focus by means of the electric motor.

This height adjustment of the front lens brings the fundus image into the focal point of the microscope objective.

As the image is completely reversed when the BIOM 4 is used, safe use is only guaranteed in conjunction with a stereoscopic diagonal inverter (SDI). The SDI rights the complete image reversal and can be switched on and off as required.

5.3 To use a BIOM 4c on SDI 3c

If this BIOM 4c (4-pin plug) should be used on the former SDI 3c (2-pin socket) version, a plug adapter (item no. 54406) is needed.
This plug adapter should be connected with the 2-pin socket in the SDI housing.
The sterile plug of the connecting cable of the BIOM 4c then needs to be connected with the adapter plug.
For dismantling the BIOM 4c, grip the plug of the BIOM 4c connecting cable and pull it out of the adapter plug.

Attention

For use of a BIOM 4c, the adapter plug (item no. 54406) has to be removed from the SDI 4c housing.

6 Operation

6.1 First-time operation

Please remove the BIOM 4 and its accessories from the packaging and dispose of the latter in the proper manner.

The BIOM and all sterilizable accessories must be cleaned, disinfected and sterilized prior to initial use and before each subsequent use.

As part of an optical system, the BIOM 4, and the operating microscope too, must be handled with care and must not be subjected to vibrations, blows or be allowed to get dirty.

6.2 Daily operation

- To mount the BIOM 4, an adapter is needed, which is customized to the type of operating microscope that is being used.
- If necessary, the adapter must be supplemented with an intermediate piece or a mounting fixture.
- Installation and instruction in the use of the BIOM 4 and its accessories will be done by an Oculus employee or by a duly authorized Oculus representative.
- A part of the mounting fixture generally remains installed at the microscope. Just like the BIOM 4 and its components, the detachable adapter plate must be cleaned, disinfected and sterlized prior to use. If, however, you do have to remove the mounting fixture for any reason, please proceed as shown on the assembly diagram provided with the adapter.
- When assembling dovetail connections, first visually check that the connection sits properly. Then tighten the knurled screw hand-tight. If the connection is correct, the dovetail connection will have no play. Check this by gently rocking the connection before you begin mounting any of the other attachments.

Attention

Detachable connections can be a source of danger if used incorrectly.

➔ Therefore, after each conversion, check that all retaining elements (e.g. locking screws) are present and are tight.

7 Use of the BIOM 4

7.1 Prior to each use

Under sterile conditions: Perform a safety function test

- ➔ Make sure that all components are present and are sterile.
- ➔ Flip the BIOM 4 towards the adapter plate. It is equipped with a swivel mechanism for 90° and a detent for this purpose.
- ➔ Make sure that the housing body can be swiveled without resistance.

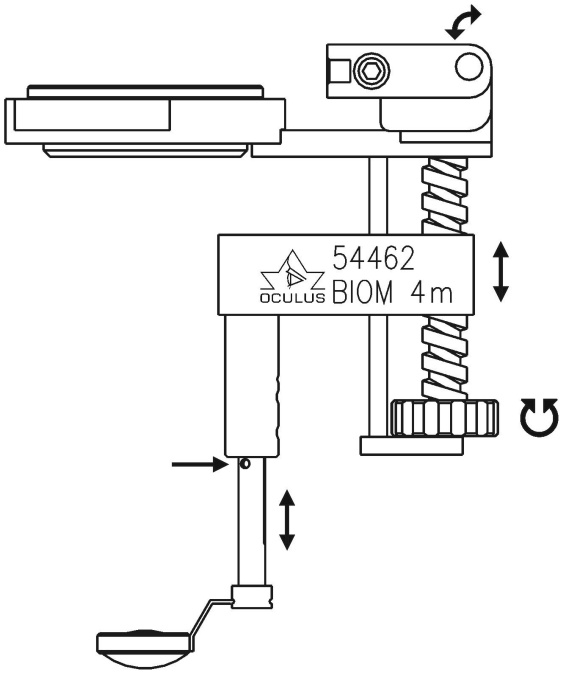


fig. 7-1: Moving Components of the BIOM

- ➔ Check that the safety slider for the lens holder runs smoothly by sliding it in and out several times by hand.
- ➔ Check that the focus adjustment wheel can be adjusted with ease, and shorten the overall length of the BIOM until the bridge is located at the top position.

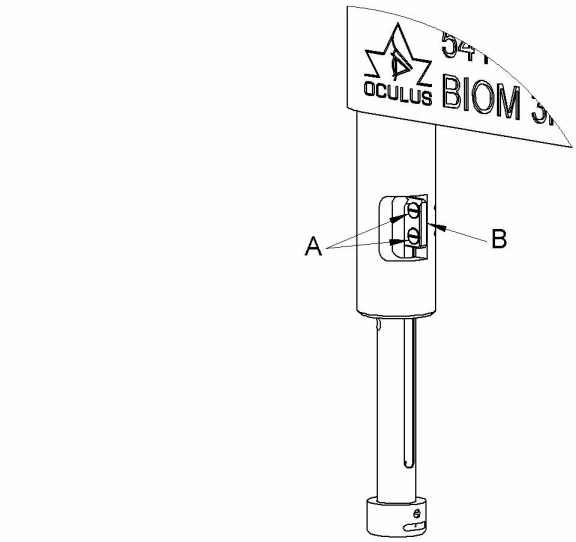
Attention

If one of these functions is not assured, the unit may not be used.

Before each use, check that

- The unit is in technically perfect condition.
- All connections and fasteners that can be loosened are properly tightened and are in a safe condition.
- The dovetail mount for the adapter is securely fastened at the micropscope.

- All fastening screws are present (e.g. screws (A) at the feather key (B) of the safety insertion)



- The detachable adapter plate and the BIOM 4 have been conditioned and sterilized
- All needed optical components for the BIOM 4 are available and are sterile

For the BIOM 4c only:

- At least one sterile drive belt is available.

7.2 Assembly and handling

All components of the BIOM 4 must be on hand and must be sterile, and must be assembled under sterile conditions.

Choose the appropriate optics

➔ Use the appropriate reduction lens for the operating microscope's objective.

➔ Select the appropriate front lens for the surgery.

fig. 7-2: Surgical Ophthalmoscopy lenses (front lenses)

- Currently available front lenses:

➔ 53606 Hi Res lens, excellent resolution, can be used with highest magnification of the microscope; the maximum field of view with this lens is approx. 60°, whereas the

working distance between the cornea and the front lens (bottom surface) is approx. 10 mm.

The outside diameter of the lens mount is 19 mm.

➔ 53604 90D lens, very good resolution; standard lens for most applications; maximum field of view with this lens is approx. 90°, whereas the working distance is approx. 8 mm.

The outside diameter of the lens mount is 19 mm.

➔ 53602 Wide-Field (E)-lens, good resolution; provides the largest field of view, large depth of field; top-selling lens, first choice of experienced surgeons; the maximum field of view with this lens is approx. 120°, whereas the working distance is approx. 3-4 mm.

The outside diameter of the lens mount is 19 mm.

➔ 53601 Wide-Field-lens for deep set eyes; the maximum field of view with this lens is approx. 70°, whereas the working distance is approx. 3-4 mm.

The outside diameter of the lens mount is 12 mm.

Note

All steam autoclavable front lenses mentioned above, have a thin, amorphous carbon coating and must be sterilized in steam autoclaves.

Disposable lens set

Beside the re-sterilizable lenses, there is also the possibility to use a disposable lens set for most types of microscopes.

fig. 7-3: Disposable lenses

The disposable lens set consists of wide field front lens with about 120° field of view, working distance approx. 3 - 4 mm. The included reduction lens is designed to work with microscope objectives with a focal length of 175 mm and 200 mm.
These lens sets can be used with BIOM 4m and BIOM 4c (not with the long versions BIOM 4ml and BIOM 4cl). The disposable lens sets are sold sterile in a box of 6 sets and cannot be sterilized again.

➔ For detailed information please see the instructions for use for the "Disposable BIOM Wide Field Lens-Set" attached to this instruction manual.

7.3 Preparing the BIOM 4 for use

Put together the complete BIOM setup from the sterile components.

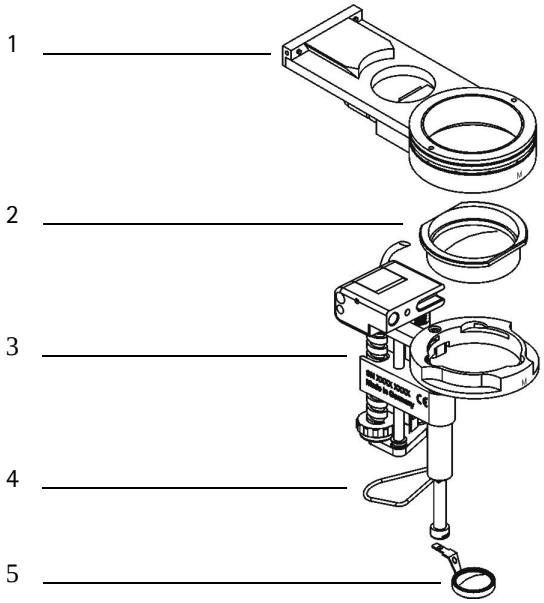


fig. 7-4: Necessary components of the BIOM 4c

1 Adapter plate
2 Reduction lens
3 BIOM 4c
4 Drive belt
5 Front lens

➔ Insert the reduction lens into the lens holder so that the side lugs sit in the recesses.

➔ Turn the reduction lens clockwise until the bayonet catch engages. It is thus held at that position.

➔ Insert the front lens into the adapter provided for that purpose. Here again, a detent prevents the lens from falling out. This detent must be overcome when inserting the lens. Make sure that the lens is properly aligned.

For the BIOM 4c only:

➔ Mount the drive belt at the BIOM 4c. For all three pulleys, the drive belt should run in the recesses provided for that purpose, otherwise the function cannot be guaranteed. When inserting the belt, begin at the groove at the bottom end of the adjusting wheel; this will make handling easier.

➔ Now, using minimal effort, slip the BIOM 4 onto the adapter plate until it reaches the limit stop. You must thereby overcome a detent that secures the connection.

Attention

Make sure that the BIOM 4 has been slipped on up to the limit stop. That is the only way that safe handling and proper centering of the image are possible.

7.3.1 Under sterile conditions: Perform a safety function test

- ➔ Make sure that all components are present and are sterile.
- ➔ Flip the BIOM against the adapter plate. It is equipped with a swivel mechanism for 90° and a detent for this purpose.
- ➔ Make sure that the housing body can be shifted without resistance.

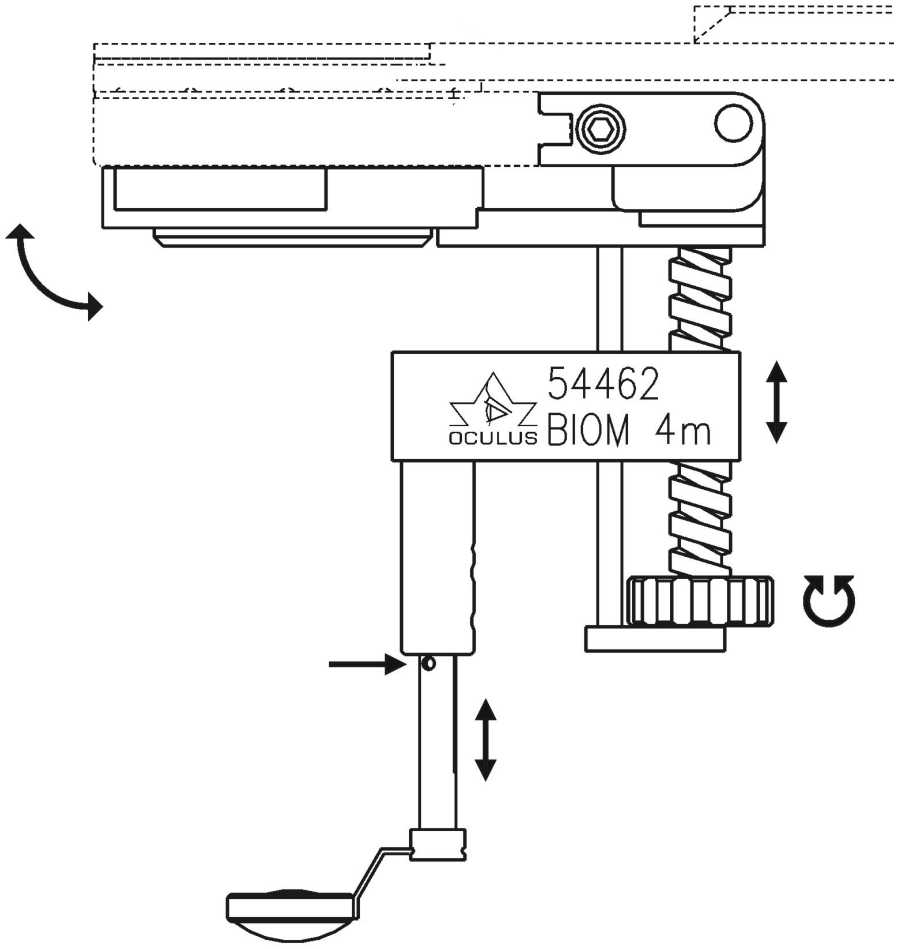


fig. 7-5: Moving Components of the BIOM 4m

- ➔ Check that the safety insertion for the lens holder runs smoothly by sliding it in and out several times by hand.
- ➔ Check the function of the focusing wheel and shorten the overall length of the BIOM until the bridge is located at the top position.

Attention

If one of these functions is not assured, the unit may not be used.

7.3.2 Connect the BIOM 4 to the microscope

➔ Slide the adapter plate with the BIOM components in compact state into the dovetail mount that is installed at the microscope. Secure the adapter into place with the knurled screw.

fig. 7-6: BIOM 4c secured in the dovetail mount

Note: For BIOM 4c only

Also connect the control cable to one of the side couplers of the SDI 4c. Make sure that the cable does not touch any unsterile parts of the microscope.

Suggestion: If surgery is to be done on the left eye, connect the control cable at the left hand side of the SDI. Or vice-versa if surgery is being done on the right eye.

For the BIOM 4c only: Installation of the cable duct

The cable duct helps to keep the connecting cable for the drive unit at the BIOM 4c (also fits BIOM 3c) away from unsterile microscope parts.

The cable duct can be sterilized in a steam autoclave and is conditioned in the same way as all other BIOM 4 components. Install the sterile cable duct at the plug and cable as shown in *(fig. 7-7, page 15)* and then connect the plug of the BIOM 4c with the socket on the SDI 4c housing.

- ➔ Fit the cable duct at the end of the plug (2) first.
- ➔ Then fit the other semi-open part (1) over the cable.
- ➔ Proceed in reverse order prior to conditioning.

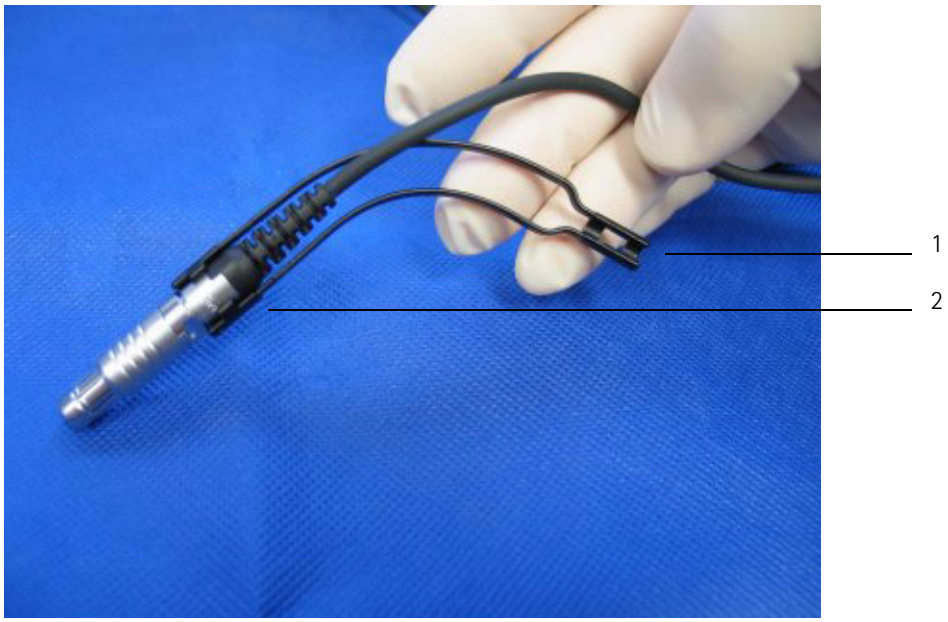


fig. 7-7: Installation of the cable duct at the BIOM 4c

Caution:

The cable duct must be removed before conditioning, otherwise sterilization is not possible.

7.3.3 Swing the BIOM 4 to the parked position

➔ During extra-ocular surgery phases, swing the BIOM out of the beam path into the parked position.

➔ When swinging out the BIOM, push in the safety slider, including the front lens, with your finger, until the slider reaches the limit stop.

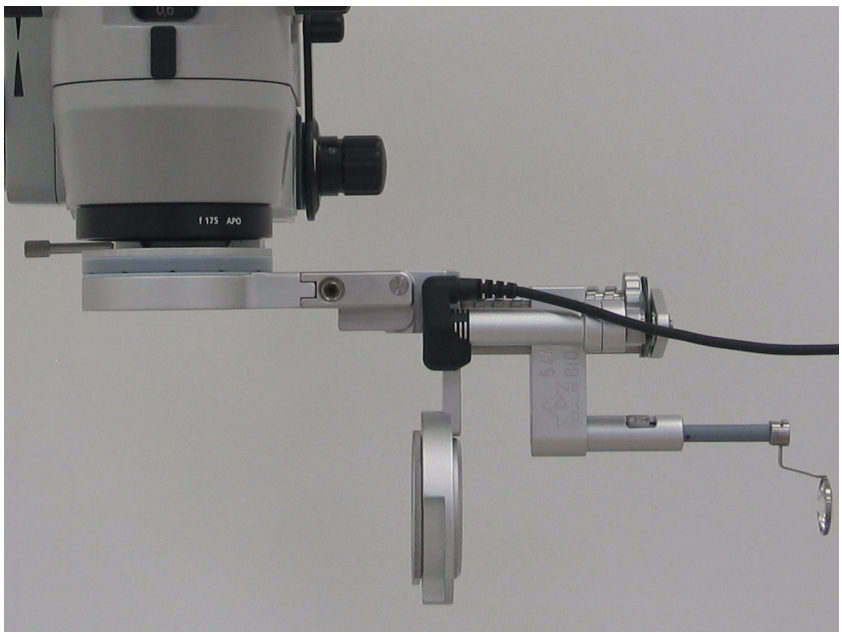


fig. 7-8: BIOM 4c at parked position

Make the basic settings at the microscope

➔ Make the basic settings at the microscope in accordance with the manufacturer's specifications.

➔ Adjust the microscope to the anterior eye segment and perform the surgery steps under microscope illumination, including insertion of the infusion.

When using the BIOM 4 focusing function, heed the following points:

- Before swinging it to the operating position, make sure that the BIOM has been set to the shortest overall length.
- Before starting the focusing process, check whether the ophthalmoscopy front lens is far enough away from the patient's eye.
- Make sure that the front lens does not come into contact with the eye.
- While focusing the BIOM, the working height of the microscope must never be adjusted, nor must the focusing function of the microscope be used.

For BIOM 4c only (focusing done by electric motor):

- Only use the BIOM 4c's motorized focusing function when the front lens is far enough away from the patient's eye.
- The surgeon may only use the motorized focusing function when the distance between the ophthalmoscopy front lens and the eye is *simultaneously* monitored.
- It must be ensured that the operator can stop the motorized focusing function at any time.

Attention

After the BIOM 4 has been swung in into the working position, the following must not be performed during the proper use:

- ➔ to use the rough adjustment mechanism of the microscope support under any circumstances (since the mechanism is not designed for precisely controlled movement).
- ➔ to change the height position of the microscope support by mechanical or motorized means whilst above the operating area.
- ➔ to change the patient´s position by raising/lowering the OP-table.

Visualization of the posterior eye segment

After all preparations for surgery in the posterior segment have been completed proceed as follows, without changing the microscope position!

- ➔ Use a suitable endoillumination.
- ➔ Swing the BIOM 4 into the beam path of the microscope. Lift up safety insertion and only release it again when the swung-in end position has been reached.
- ➔ The lens slides down to its designated position. This position has been reached when the control marks are fully visible.
- ➔ Turn off the microscope illumination.
- ➔ Activate the SDI to right the complete image reversal.

➔ **For BIOM 4c and SDI 4c only:**

- If the BIOM 4c is swung out of the beam path the inverter function is not activated.
- While swinging the BIOM 4c into working position the SDI 4c is activated automatically.
- The position switch on board of the BIOM 4c thus operates the re-inverting function.
- If another status of the inverter is desired, the SDI 4c can be optionally operated via a combi foot switch.

- ➔ At a low microscope magnification: Begin initial focusing of the BIOM 4-image by turning the BIOM 4 focus adjusting wheel.
- ➔ Magnify the image section by actuating the focus foot switch at the microscope.

➔ Then use the microscope footswitch control to zoom in to maximum magnification. Now finely focus the image with the adjusting knob of the BIOM 4.
Only thus is a parfocal image (i.e. a sharp image at every magnification) guaranteed!

➔ **For the BIOM 4c only:**
Adjust the sharpness of the image with the rocker of the combination foot switch, both for initial focusing and for parfocally setting the image.

➔ The microscope magnification should then be reduced to the minimum required, in order to achieve as wide a fundus view as possible.

➔ The use of the focusing function with the microscope foot pedal when the BIOM 4 is in use only changes the size of the image field ("keyhole effect").

Attention

During the whole process, make sure that the front lens cannot come into contact with the cornea!

The cornea must be kept moist with a suitable fluid, to protect the cornea and to achieve a good and clear view of the fundus.

Swing the BIOM 4 back to its parked position

➔ After completing the surgery in the posterior segment, slide the safety insertion of the BIOM 4 upwards by hand and swing the BIOM aside.

➔ Deactivate the SDI.

➔ **For BIOM 4c and SDI 4c only**:
Swinging the BIOM 4c aside deactivates the SDI 4c.

Remove the BIOM 4 from the microscope

➔ After completing the surgery, loosen the knurled screw and remove the BIOM 4, including the adapter plate, from the dovetail mount.

➔ **For the BIOM 4c only:**
Also disconnect the plug of the BIOM 4c-drive unit from the coupler at the SDI 4c housing. Only pull on the corrugated sleeve of the plug (fig. 7-9, page 19). When the plug is pushed into the socket, the plug locks into place automatically. The lock can only be released by pulling on the corrugated sleeve.

Note

Always grip the plug of the BIOM 4c at the sleeve, in order to release the lock. Pulling on the cable itself could damage it and the complete drive module would then have to be exchanged.

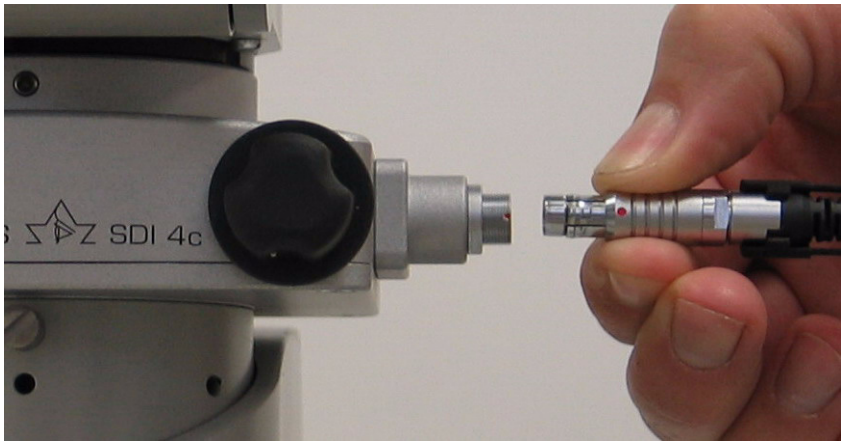


fig. 7-9: Unlocking the BIOM 4c plug

Conditioning of the components

- The BIOM 4 and all BIOM components must be sterilely conditioned prior to the first, and every subsequent use.
- It is imperative that you heed the cleaning, disinfection and sterilization instructions given in the "Conditioning manual for BIOM and accessories".

fig. 7-10: Specially designed insert for sterilization containers. Loaded with the BIOM 4c-setup

Dismantling of the BIOM 4

- For dismantling proceed in reverse order from assembly of the BIOM 4.
- The BIOM 4 can be removed from the adapter only when tilted to the side. Dividing these two items for cleaning, desinfection and sterilization is absolutely necessary.
- Swivel the BIOM 4 out and away until it clicks into horizontal position. Now pull the BIOM 4 off the adapter. In doing so, the resistance of the lock must be overcome.
- Also dismount the two optics before you clean, disinfect and sterilize all components in a steam autoclave.

- **For the BIOM 4c only:**
  Proceed as mentioned above.

  Furthermore remove the drive belt and the cable duct from the BIOM 4c.

  All components are now prepared for cleaning, disinfection and sterilization in a steam autoclave.

7.4 Practical application tips for the BIOM 4

Attention

Take suitable measures to suppress uncontrolled head movements of the patient during the surgery. These could cause injury to the patient.

Any contact of the front lens with the cornea must be avoided in general.

If, however, the lens does happen to come into contact with the cornea, the image will immediately become blurred. In an extreme emergency, e.g. an uncontrolled downward movement of the microscope, that cannot be stopped using the emergency stop switch on the microscope, pull or move the complete operating microscope upwards, or shift the BIOM 4 out of the beam path.

After a contact between front lens and the eye, swing the BIOM 4 out, or slide the safety insertion upwards to facilitate cleaning of the optics, so that you can clean the lens with a sterile swab.

Make sure that the cornea is sufficiently moistened with a suitable solution. This will prevent damage to the cornea and will give you the optimal view into the eye.

Using the focus of the microscope during use of the BIOM 4, creates a field aperture effect. The greater the distance between the eye and the microscope, the smaller the angle of observation. This leads to the so-called "keyhole effect".

Focusing on the BIOM 4 is done manually with the adjusting wheel and can also be done by a sterile assistant, who follows the surgery via a co-observer viewer.

➔ **For the BIOM 4c only:**

Focusing of the BIOM 4c is done solely by the surgeon by means of the combination foot switch while observing through the microscope.

Note

Adjust the ophthalmoscopy front lens rather upwards for hyperopic eyes and downwards for myopic eyes.

8 Troubleshooting

Attention

If an error occurs which you are unable to correct by following the instructions below, label the device as "out of order" and contact our service department. (Address: *sect. 12.3, page 28)*

Troubleshooting guide - BIOM 4

Fault	Possible Cause	Help
The safety extension of the BIOM 4 is stuck BIOM 4 must not be used in this condition !	Deposits on the BIOM 4 due to inadequate sterilization Foreign body in safety rod extension channel	Careful mechanical cleaning, use of another sterilizing agent, use ultra sonic bath Careful mechanical cleaning and removal of the foreign body Cleaning the BIOM 4 in the ultrasonic bath Treat the slider with a suitable, silicone oil-free lubricant prior to the next sterilization
Adapter wobbles Dovetail mount wobbles	The knurled head locking screws are loose Screws are loose	Tighten the locking screws by hand Tighten the screws with a suitable screwdriver
Image is cropped or out-of-center	The SDI, other components, or the BIOM 4 adapter are incorrectly mounted at an angle The front lens clip is bent or mechanically damaged	Correct the assembly Carefully bend the front lens clip back into shape or senr it to our service address for adjustment
Unclear image	Soiled glass surfaces The glass surfaces have been damaged during sterilization The glass surfaces have been mechanically damaged The ophthalmoscopy front lens is in contact with the eye Dry patient cornea	Clean the glass surfaces Change the sterilization method, replace lenses if necessary Greater care in use and storage of lenses; replace if necessary Correct the working distance, clean the lens surfaces Moisten the cornea regularly with a suitable solution
Unfocused image	Incorrect adjustment of the BIOM 4 A reduction lens is not being used The reduction lens is not compatible with the microscope objective	Focus the BIOM 4 in accordance with the instructions Use a reduction lens Check the engraving on the reduction lens and exchange it, if necessary (refer to "Optical Components, Pg. 29)

Fault	Possible Cause	Help
Fundus view is too narrow	Too much distance between the ophthalmoscopy lens and the eye Magnification of the microscope system to high	Carefully reduce the distance using the microscope fine adjustment mechanism Reduce magnification of the microscope
The eye or the lens reflect strongly	The microscope light is on	Turn the light off, illuminate only intraocular
The BIOM 4 cannot be detached from the adapter	BIOM 4 has not been tilted to the side for disassembly Vacuum has developed between the BIOM 4 and the adapter, or there are deposits on the connecting parts	Tilt the BIOM 4 to the side Place the BIOM 4 and adapter into an ultrasonic bath (for approx. 5 min)

only BIOM 4c

No function whatsoever when the combination foot switch is actuated	The combination foot switch is not connected to the SDI 4c The SDI 4c is not connected to the 6V-15V power supply Power failure or power outlet is not active The electric sockets on the support are in use but inactive	Establish the connection to the SDI 4c Establish the connection to the 6V-15V power supply Inform the in-house electrician Use the 6V-15V plug transformer Use the mechanical adjusting element or adjusting wheel Activate the sockets in accordance with the instructions for the stand Ask the microscope manufacturer for assistance
Malfunciton when using the combination foot switch	5-pole plug has been forcibly plugged in the wrong way round	Plug it in the right way round (pay attention to the lug and slot of the polarity reversal protection)
Motorized focusing not possible with the BIOM 4c when using the combination control unit	BIOM 4c connector not plugged into the SDI 4c properly Defective drive belt Drive belt missing Connecting cable damaged Defective drive module	Plug in the connector correctly Install a new sterile drive belt or focus manually using the focusing knob at the BIOM 4c Install a sterile drive belt Exchange the drive module Exchange the drive module

9 Exchanging the BIOM 4c Drive Module

Attention

Handle the drive module and the clutch disk with care!

The drive module has a magnetic coupling. Strong magnetic forces!

Risk of injury!

- ➔ Dismount the BIOM 4c from the microscope and remove the drive belt.
- ➔ Remove only the one hexagon socket head screw (allen screw) M2.5 (key size 2), which holds the drive module in place on the triangular base plate.
- ➔ Slightly move the drive unit from side to side while pulling it out of the position.
- ➔ Clean the clutch disk of the magnetic clutch that is mounted on the base plate.
- ➔ Install the new drive module.

  To do so, insert the square shoulder of the drive module the correct way round into the square recess in the triangular base plate.
- ➔ Now fasten down the drive module with a new hexagon socket head screw.

  Use only the supplied, self-locking hexagon socket head screw M2.5x4 (with blue adhesive coating).

Attention

Heed the assembly instructions provided with the drive module.

10 Care and Maintenance

Attention

Please heed the separate Conditioning manual.

Note

The sterilization insert from the company Oculus Optikgeaete GmbH (Art. No. 54185) can also be used for cleaning the BIOM components in a washer.

General

- ➔ Do not use aggressive cleaning agents that contain chlorine or solvents, nor abrasive or sharp-edged cleaning products to clean the unit.
- ➔ Always heed the product descriptions and directions for use of products you use to desinfect.
- ➔ Due to the special surface finish required for sterilizability of the BIOM 4, structural patterns may become visible. This unavoidable minor blemish does not in any way adversely affect the function, handling and sterilization of the unit.

Care of the BIOM 4

- ➔ After cleaning and prior to sterilization, treat all moving parts of the BIOM 4 with a sterilizable, silicone-oil-free conditioning lubricant.
- ➔ Remove any excess oil from the surfaces, as staining could otherwise occur.
- ➔ The following can be used for this purpose: Aesculap Sterilit i (JG600) oilspray or Medicon Instrumentensprühöl 46.00.40.

Cleaning and sterilizing the BIOM 4

- ➔ Clean the BIOM 4 with water immediately after use. This prevents incrustations which can make sterilization impossible.
- ➔ The BIOM 4 can be cleaned and disinfected in a dishwasher with a mildly alkaline detergent, as well as in the disinfector (refer to the Conditioning manual).
- ➔ All components of the BIOM 4 listed in Chapter 14 can be sterlized in a steam autoclave (max. 134°C / 273°F). Always remove the optical system components before autoclaving.

Attention

Use only demineralized, filtered water for steam sterilization. Only in this way do you protect the unit against deposits which can adversely affect its function.

➔ Take care when sterilizing the BIOM 4 that the safety extension rod is completely pulled out. This permits a free flow of steam through the hollow spaces of the unit.

- The Oculus Optikgeaete GmbH company offers a sterilization-container with a specially designed inset keeping the BIOM 4, optical components and the adapter plate in place for optimum care during and after sterilization.

Attention

Sterilization of the BIOM 4 using STERRAD® is not allowed. It may damage the BIOM 4.

Cleaning and sterilizing the adapter

➔ Dismount the adapter plate from the BIOM 4, as this is the only way to ensure satisfactory cleaning and sterilization of this component and of the BIOM 4.

➔ Clean the adapter by wiping it off with a damp cloth.

➔ The adapter can be cleaned and disinfected in a dishwasher with a mildly alkaline detergent, as well as in the disinfector (refer to the Reconditioning Manual).

- All BIOM 4 adapters provided by us are autoclavable with steam (max. 134°C/273°F).

Attention

Sterilization of the BIOM 4 adapters using STERRAD® is not allowed. It may damage the adapters.

Cleaning and sterilizing the reduction lens and the ophthalmoscopy lens

➔ Dismantle the optical components of the BIOM 4 before cleaning and sterilizing it.

➔ Clean the optical system with water immediately after use. This avoids incrustations which can make complete sterilization more difficult.

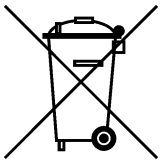
The optics (lenses) can be cleaned and disinfected in a dishwasher with a mildly alkaline detergent, as well as in the disinfector (refer to the conditioning manual).

➔ Under no circumstances should the optical system be autoclaved while being mounted on the BIOM 4. The presently available reduction lenses and front lenses, with the exception of disposable lenses sets, can be sterilized in a steam autoclave at a max. temperature of 134°C / 273°F. To prevent water stains on the optics, the front lenses and reduction lenses should be kept in a vertical position during sterilization.

- The optics can be double shrink-wrapped or secured in the sterilization inset from Oculus Optikgeaete GmbH, for sterilization in the autoclave.
- Please be sure to heed the additional instructions given in the specific conditioning manual that are provided with all sterilizable OCULUS products and sterilization and disinfection systems.
- Avoid damage to the surface and its coating. Always place the optical components on a soft surface.

11 Disposal of Used Devices

In accordance with Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003, and in accordance with German law governing the circulation, return and environmentally friendly disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.



12 Warranty and Service

12.1 Warranty

The device you have purchased is a high-quality OCULUS product. This device was carefully manufactured using quality materials and modern production methods. Any software included in the delivery was tested by us and complies with technical standards. Prior to and while operating the device it is important that you observe the instruction manual and safety instructions.

The device carries a warranty to which you are entitled in accordance with the legal provisions.

If the unit is tampered in any way by non-authorized persons, all warranty claims are rendered null and void, because improper modifications, maintenance and repairs can lead to considerable hazards for the user and the patient.

In the event of transport damage, we request that you notify the shipping company immediately and have the damage confirmed on the consignment note, to enable a proper claims settlement procedure.

Overall, the general terms and conditions of business and delivery apply as per the date of purchase.

12.2 Assumption of liability for functions and damage

Oculus Optikgeaete GmbH will only accept responsibility for the safety, reliability and serviceability of the unit if the BIOM 4 is used in compliance with the instructions contained in this instruction manual.

OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorised personnel, if the unit is maintained improperly or if it is handled incorrectly.

12.3 Manufacturer's and service addresses

Our service department or authorised representatives will furnish you with additional information.

Manufacturer - Service Addresses:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhaeuser Str. 29
D - 35582 Wetzlar, Germany
Tel.: ++49 641/2005-0
Fax: ++49 641/2005-295
E-mail: sales@oculus.de

13 Declaration of Conformity

We declare under our sole responsibility that this product meets the fundamental requirements of Annex 1 of Directive 93/42/EEC of 14th June, 1993 for medical products.

Following harmonized standards were employed to verify the above mentioned requirements:

-DIN EN ISO 15004

CE

according to the regulations of MDD

Dipl.Ing. Rainer Kirchhübel

Management
OCULUS Optikgeräte GmbH

14 Order Information, Accessories and Replacement Parts

Basic unit

Component	Order number
BIOM 4c	54400
BIOM 4cl	54403
BIOM 4m	54462
BIOM 4ml	54463

Accessories for the BIOM 4c / BIOM 4cl

Component	Order number
Drive belts (pack of 10)	54176
Cable duct (pack of 5)	54178

Adaption components for BIOM 4

Component	Order number
Adapter for Zeiss Retrolux 1/3	54421
Adapter for Zeiss Retroskop 1/2	54422
Adapter for Zeiss OPMI MDI/MDO/MDU/Retrolux CS/VISU/Lumera	54423
Adapter for Zeiss OPMI 6	54424
Adapter for Zeiss Retroskop CS	54428
Adapter for Takagi OM 18	54418
Adapter for Moeller/WedelOphtamic 900/Hi-R 900	54440
Adapter OPMI VISU with VISULUX slitlamp	54431
Adapter for Topcon OMS 600/OMS 610/ OMS 650/ OMS 800 Pro/OMS 800 Standard/OMS 710	54441
Adapter for Topcon OMS 110	54442
Adapter for Leica M690 with 0°-Coobserver	54444
Adapter for Leica M500/M501/M620	54445
Adapter for Leica M690	54446
Adapter for Leica M841/M820/M844	54448
Dovetail for Zeiss OPMI VISU/Lumera	54511
Distancing part for ring support objective at Zeiss OPMI 6	54535
Adaption part for 0°-Coobservation holder at Zeiss OPMI 6	54536
Dovetail for Zeiss OPMI 1/6	54537
Dovetail for Zeiss MDO/Retrolux CS	54538
Distancing part Zeiss OPMI MD	54539
Distancing part for Möller Ophtamic 900 mit 20°-illumination unit	54639

Sterilization components for BIOM 4

Component	Order number
Sterilization-Container with inset for BIOM 4 and accessories	54180
Inset for steri-container	54185
Paper filters for steri-container (1000 pcs/box)	54190
Seals for steri-container (1000 pcs/box)	54194
Indicator labels for steri-container (1000 pcs/box)	54193
Autoclavable adhesive tape with steam indicator, 50 m long, 19 mm wide	54192

Optical components for BIOM 4

Reduction lenses

Component	Order number
Reduction lens for f = 175 mm	54547
Reduction lens for f = 200 mm	54545
Reduction lens for f = 225 mm	54548
Reduction lens for Retroskop	54544

Ophthalmoscopy front lenses

Component	Order number
Autoclavable lenses:	
Wide-Field-lens, Diameter 12 mm for BIOM 4	53601
Wide-Field-(Enhanced)-lens for BIOM 4	53602
90 D-lens for BIOM 4	53604
Hi Res-lens for BIOM 4	53606

Disposable lens set

Wide field lens set, including reduction lens for objective focal lengths of f=175 and f= 200mm (disposable, pack of 6), not to be used with BIOM long version	53595

Image Inverting Systems for BIOM 4

Component	Order number
SDI 4c (6-15 V)	54320
SDI 4e (6-15 V)	54300
SDI 4m (mechanical)	54302
Types for Leica-microscopes:	
SDI 4c (6-15 V)	54330
SDI 4e (6-15 V)	54310
SDI 4m (mechanical)	54312

15 Technical Data

Dimensions BIOM 4m and 4c

Width	63 mm
Depth	111.5 mm
Height	110 - 145 mm
Total height	approx. 123-158 mm
Range of safety extension rod	approx. 29mm

Dimensions BIOM 4ml and 4cl

Width	63 mm
Depth	111.5 mm
Height	124 - 160 mm
Total height	approx. 137-173 mm
Range of safety extension rod	approx. 29 mm

Weight

BIOM 4m and BIOM 4 c	approx. 260 g
BIOM 4ml and BIOM 4cl	approx. 265 g
Reduction lens	approx. 20 g
Ophthalmoscopy front lens	approx. 10 g

Operating conditions with optical system

Temperature	+10 °C (50° F) to +40 °C (104˚F)
Humidity	30% to 70%
Air pressure	700 hPa to 1060 hPa

Sterilization and disinfection procedures

BIOM 4	steam autoclaving, max. 134°C (273° F)
Reduction lens (only the reduction lenses listed in this manual)	steam autoclaving, max. 134°C (273° F)
Ophthalmoscopy front lens (only the lenses listed in this manual)	steam autoclaving, max. 134°C (273° F)
Adapter	steam autoclaving, max. 134°C (273° F)
Drive belt	steam autoclaving, max. 134°C (273° F)

Symbols on the instrument

The instruments meets the requirements of the specified standard:

CE

Follow the instruction manual:

Type B application:

Type of device protection:

IP 64

The unit can be attached to the following microscopes:

- Zeiss:
  OPMI 1/6
  OPMI CS with Retrolux 1/3/CS
  OPMI CS withRetroskop 1/2/CS
  OPMI MDI/MDO/MDU
  OPMI VISU 150/ VISU 160
  OPMI VISU 200 / VISU 210
  OPMI Lumera
  OPMI Lumera T

- Leica:
  M500 / M501 / M620
  M650 / M690
  M820 / M840 / M841 / M844

- Moeller:
  Ophtamic 900 / Hi-R 900 / EOS 900

- Takagi:
  OM 18

- Topcon:
  OMS 600 / OMS 610 / OMS 650
  OMS 110
  OMS 710
  OMS 800 Standard / OMS 800 Pro

- Kaps:
  SOM

Disposable BIOM Wide Field Lens-Set for f=175mm and for f=200mm
Order no.: 53595
Instructions for use

Description: Disposable lenses for use with the BIOM 4 model wide-angle viewing system from Oculus.

Parts include: (1x) Disposable wide-field lens,
(1x) Disposable reduction lens for use with an f=175 mm or f=200 mm objective lens.

Warning: Never use a product that appears to be damaged!

Directions:
Non- Sterile personnel

1. Check the packaging for damage. The product must not be used if any damage is found on the packaging.
2. After a visual check, open the outer plastic wrapping without touching the inner fleece packing of the lenses.
3. Let the lenses, which are packed in sterile fleece, slide on to a sterile surface. Make sure that the sterile lenses are not contaminated during this process.

Sterile Operating Nurse/Surgtech

4. Remove the lenses from the fleece packing without touching the lens surface.
5. Hold the reduction lens (A) by its black plastic ring and place it in the Biom´s lens holder (B) so that the mounting ring tabs on the lens fit into the notches in the lens holder.
6. Turn the reduction lens clockwise, passing through the resistance of the spring clip. The reduction lens is now secure and will not fall out.
7. Using your thumb and index finger, hold the wide-field lens (D) on either side of the black arm without touching the lens surface. (**Figure 1***)* Failure to hold the clip in this regard may result in the premature breaking of the clip. The lens is correctly orientated if its position matches the diagram below. (**Figure 2**) Fasten the lens by inserting the black plastic tab into the slot (C) of the Biom lens holder passing the resistance until the small outer tabs click and lock into position.
8. To remove the lenses after use, grasp the wide-field lens clip in the “front” (**Figure 3**) and simply break the lens clip in a firm downward motion. Next, remove the “back” portion clip and discard. Turn the reduction lens counter clockwise and carefully lift out of the lens ring holder.

Sterilization:

These lenses are delivered in a sterile condition and are intended for *SINGLE USE ONLY*. After surgery they should be properly disposed of according to contaminated medical waste guidelines of your facility.
If sterile packaging appears damaged, do not use this item

STERILE EO

LATEX

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